

Exhibit C

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1 causation; and in medicine, we apply the
2 reasonable medical certainty threshold,
3 which means more likely than not.

4 So that is the background
5 that I used when evaluating this
6 question.

7 Q. Is there a difference in
8 your understanding between the question
9 of general versus specific causation?

10 A. Yeah, I would understand
11 them to be different insofar as, in a
12 general case, I'm opining about the
13 plausibility of this adverse event or,
14 you know, if we take it away from the
15 Benicar question and just say in general,
16 for any stimulus, is it likely that this
17 stimulus causes this event --

18 Q. In the general population?

19 A. I wouldn't necessarily say
20 in the general population, because there
21 are different -- populations can be
22 affected by diseases differently. So,
23 for instance, in celiac disease, gluten
24 can affect genetically predisposed

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1 question and I'm not sure that I
2 would put that particular label on
3 it.

4 BY MR. PARKER:

5 Q. And that's what I'm trying
6 to drive at. What do you have to have
7 when you come into the doctor, what
8 complaints, what findings by the doctor
9 do you have to have, before, as you put
10 it, the label goes on the patient?

11 MR. SLATER: Objection to
12 the form of the question;
13 foundation.

14 You can answer.

15 MR. PARKER: And if this is
16 outside your area of expertise,
17 just tell me and I'll move on, but
18 I thought you said you felt
19 comfortable answering the
20 question.

21 MR. SLATER: And objection
22 to that lead-in just now.

23 You can answer.

24 THE WITNESS: Well, I think

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1 it's really at the judgment of the
2 treating physician.

3 BY MR. PARKER:

4 Q. So it can be anything if in
5 the judgment of the treating physician --
6 something as abdominal pain for a couple
7 days, in that physician's mind, that can
8 qualify for a label of sprue-like
9 enteropathy associated with olmesartan?

10 A. I think that you would have
11 more definite and less definite cases and
12 I think if you are the treating
13 physician, your interest is the results;
14 and if someone had minimal abdominal pain
15 for three -- you know, for a few days and
16 stopped taking olmesartan and they
17 improved, I would not personally find
18 that to be a very plausible case of
19 sprue-like enteropathy.

20 But if you're trying to
21 whittle -- you know, kind of get to the
22 exact criteria, I don't think that we're
23 there yet. I don't think that we have --
24 we've seen a fairly wide presentation as

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1 far as both symptoms and histopathology
2 and a lot of it has been very serious.
3 So it's not just, you know, a couple days
4 of mild pain. It's -- we've seen some,
5 as you're aware, very significant --
6 significantly ill patients.

7 And so I -- in my experience
8 at Columbia anyway, the patients who I've
9 seen labeled as sprue-like enteropathy,
10 there's not been one of them that I've
11 doubted the diagnosis and it hasn't been
12 a specific point that, oh, because of --
13 because of X, then Y. It's been, you
14 know, taking into account the entirety of
15 the clinical picture.

16 Q. I think, however, Doctor,
17 what -- in answer to my question about
18 what are the clinical criteria, I think
19 you're telling me we're not there yet in
20 the medical community. Am I correct?

21 MR. SLATER: Objection;
22 mischaracterization.

23 You can answer.

24 THE WITNESS: Well, I'm

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1 saying that there are varied
2 clinical presentations and varied
3 pathologic presentations; and,
4 therefore, it requires the
5 patient's doctor to make a
6 reasonable assessment based on the
7 entire clinical picture.

8 BY MR. PARKER:

9 Q. Let me approach it this way:
10 Doctor, if we went into the medical text,
11 I would be able to find the criteria for
12 diagnosing celiac disease; correct?

13 A. Yes.

14 Q. If I went into the medical
15 text, I could find the criteria for
16 diagnosing autoimmune enteropathy;
17 correct?

18 A. You could find some listings
19 of criteria.

20 Q. If I were to go into --

21 A. May I make a point?

22 Q. Sure, yes. As long as it's
23 answering my question.

24 A. Okay. I think that

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1 trials of azilsartan medoxomil for
2 purposes of writing this paper?

3 A. No.

4 Q. Do you recall who did that?

5 A. Who referenced the reference
6 28, you mean?

7 Q. Who reviewed the clinical
8 trials of azilsartan.

9 A. You mean who found article
10 28 and included it in the statement.

11 Q. And studied it, presumably.

12 A. I don't.

13 Q. Okay. Let's go on then.

14 Down at the bottom of
15 section 5, I think this confirms what you
16 said earlier, but let me just make sure,
17 you wrote: This broadens the
18 differential even further and there is no
19 cardinal finding which can establish the
20 diagnosis of olmesartan-induced injury
21 based on histopathology.

22 That remains your view
23 today.

24 MR. SLATER: You didn't read

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1 it completely accurately, but you
2 can answer.

3 MR. PARKER: Well, I
4 certainly wanted to, so I'll try
5 it one more time.

6 MR. SLATER: I know what you
7 wanted to. I know what you desire
8 in life. Just making an
9 objection.

10 BY MR. PARKER:

11 Q. "This broadens the
12 differential even further and there is no
13 cardinal finding which can establish the
14 diagnosis of olmesartan-induced injury
15 based solely on histopathology," does
16 that remain your opinion today?

17 A. It does.

18 Q. Under celiac disease,
19 section 5.1, the last sentence,
20 "Ultimately, seronegativity and ARB use
21 are the most meaningful discriminators
22 between celiac disease and ARB
23 enteropathy," does that remain your
24 opinion today?

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1 we're evaluating those questions, but
2 I've never -- I've never, you know,
3 specifically written a paper in which I
4 looked at each point and made a response.

5 Q. I take it from your last
6 answer that in the period of time that
7 you were writing your general causation
8 report, you were aware of and understood
9 the Bradford Hill factors criteria.

10 A. I was familiar with the
11 criteria.

12 Q. And what is their use in
13 medical science?

14 A. They are a set of questions
15 which are used to address cause and
16 effect.

17 Q. Can you explain for me why
18 that methodology was not used in your
19 report?

20 A. I think it influences my
21 thinking, those points influence my
22 thinking. I didn't explicitly go through
23 them because -- I don't know. Just did
24 not do that.